IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, v. Arthrex, Inc. a Delaware Corporation Defendant.	)	Civil Action No. 04-12457 PBS

DEFENDANTS' REPLY TO MITEK'S FACTS SUBMITTED IN RESPONSE TO ARTHREX'S SUMMARY JUDGMENT MOTION

Pursuant to Rule 56.1 of the Local Rules, District of Massachusetts, Defendants Arthrex, Inc. ("Arthrex") and Pearsalls, Ltd. ("Pearsalls") (together, "defendants") hereby submit their Reply to Mitek's Facts in Response to Arthrex's Summary Judgment Motion ("Defendants' Reply Facts").

Mitek Fact #128: Disputed. This statement misstates the language of the claims of the '446 patent. Reply Ex.[1] 4.

Mitek Fact #129: Disputed. This statement is vague and indefinite and is an attempt to mislead the Court. Dr. Brookstein never mentions any specific "uses." UHMWPE is for highly specialized uses that are unrelated to the 446 patent. Reply Exs. 6, 23.

[1] "Reply Ex." refers to the exhibits attached to Defendants' Reply in support of their Summary Judgment Motion.

Mitek Fact #130: Disputed. Dr. Mukherjee explained that "PE," as described and claimed in the '446 patent does not include UHMWPE. Opp.Ex.[2] 6 at 10-14. Dr. Mukherjee also explained that there is a substantial difference between UHMWPE and the first fiber-forming materials of claim 1 of the '446 patent. Opp.Ex. 6 at 14-17. *See also* Defendants' Reply in Support of their Summary Judgment Motion ("Def.'s Reply") at 4-10, and support cited therein.

Mitek Fact #131: Disputed. Dr. Mukherjee explained that "PE," as described and claimed in the '446 patent does not include UHMWPE. Opp.Ex. 6 at 10-14. Dr. Mukherjee also explained that there is a substantial difference between UHMWPE and the first fiber-forming materials of claim 1 of the '446 patent. Opp.Ex. 6 at 14-17. *See also* Def.'s Reply at 4-10, and support cited therein.

Mitek Fact #132: Disputed. These are not characteristics of preferred embodiments, but rather of the claims themselves because the broad claims were abandoned and the issued claims are to the very embodiments that DePuy Mitek wrongly calls preferred embodiments. Opp.Ex. 27. This statement is also incomplete and designed to mislead the Court. The '446 patent specification suggests that while a braid made entirely of "highly lubricious polymers" can be used to make a highly pliable braid, such a braid "will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments." This theme that highly pliable, lubricious polymers are too weak for suture usage is repeated when the specification explains that the pliable yarn from the set need to be combined with a strength yarn from the second set and a "volume fraction of lubricating yarns . . . above 80% may adversely affect the overall strength of the braid." The specification then explains that the proposed solution is to have a suture comprised of a heterogeneous braid made

[2] "Opp.Ex." refers to exhibits attached to Defendants' Opposition to DePuy Mitek's Summary Judgment Motion.

of two different fiber forming materials which exhibits "improved pliability and handling properties . . . without appreciably sacrificing" [the suture's] physical properties," namely its "physical strength and knot security." This proposed solution is repeated throughout the specification. The '446 patent specifically refers to "pliability" in connection with "resistance to bending," and "bending rigidity," which are the inverse of pliability. A handling property specifically identified in the '446 patent is "knot tie down." The '446 patent relies on what is called the "rule of mixtures" to attempt to demonstrate that this combination is an improvement in the art. The point made by the inventors is that gains in pliability and handleability by using the combination of highly pliable and lubricious, but relatively weak, materials with a stronger material outweighs the loss of suture strength. Reply Ex. 4 at discussions through cols, 2, 4,6, and 8 and Table. *See also* Def.'s Reply at 4-10, and support cited therein.

Mitek Fact #133: Disputed. FiberWire does not contain PE. Rather it contains UHMWPE, a substance that is not included within the meaning of "PE," as that term is described and claimed in the '446 patent. *See* Opp.Ex. 6 at 10-18; Opp.Ex. 14; Opp.Ex. 15; Opp.Ex. 11. Dr. Mukherjee also explained that there is a substantial difference between UHMWPE and the first fiber-forming materials of claim 1 of the '446 patent. Opp.Ex. 6 at 14-17. *See also* Def.'s Reply at 4-10, and support cited therein.

Mitek Fact #134: Disputed. FiberWire does not contain PE. Rather is contains UHMWPE, a substance that is not included within the meaning of "PE," as that term is described and claimed in the '446 patent. *See* Opp.Ex. 6 at 10-18; Opp.Ex. 14; Opp.Ex. 15; Opp.Ex. 11. Dr. Mukherjee also explained that "PE," as described and claimed in the '446 patent does not include UHMWPE. Opp.Ex. 6 at 10-14.

Mitek Fact #135: Disputed. FiberWire does not contain PE. Rather it contains UHMWPE, a substance that is not included within the meaning of "PE," as that term is described

and claimed in the ‘446 patent. *See* Opp.Ex. 6 at 10-18; Opp.Ex. 14; Opp.Ex. 15; Opp.Ex. 11. Dr. Mukherjee also explained that “PE,” as described and claimed in the ‘446 patent does not include UHMWPE. Opp.Ex. 6 at 10-14.

Mitek Fact #136: Disputed. This statement is designed to mislead the Court and has no support in the record. When Dr. Brookstein described the function of PET in his Expert Report, he only asserted that PET’s function is to provide flexibility. There is not a word about strength. Reply Ex. 1 at ¶ 56. What Dr. Brookstein describes as a strength is a made up term that has nothing to do with strength and certainly has nothing to do with strength as that term is used in the ‘446 patent. Without question, the patent’s description of strength is speaking of tensile strength of the materials, going so far as to describe the specific amount of yarn tenacity that is desired. Reply Ex. 4 at col. 4, ll. 36-39. Moreover, UHMWPE does not perform the functions of the first set of yarns as set forth in the 446 patent. Opp.Ex. 6 at 14-17. *See also* Def.’s Reply at 4-10, and support cited therein. *See also* Response to Mitek Fact #132.

Mitek Fact #137: Disputed. This statement is designed to mislead the Court. FiberWire does not contain PE. Rather it contains UHMWPE, a substance that is not included within the meaning of “PE,” as that term is described and claimed in the ‘446 patent. *See* Opp.Ex. 6 at 10-18; Opp.Ex. 14; Opp.Ex. 15; Opp.Ex. 11. Dr. Mukherjee also explained that “PE,” as described and claimed in the ‘446 patent does not include UHMWPE. Opp.Ex. 6 at 10-14. Dr. Brookstein simply makes up the word “knot holding strength” to describe what is the well-known property of knot security. Dr. Brookstein cites to nothing for this made up term. Reply Ex. 2 at ¶ 20. Moreover, Dr. Brookstein’s false assertion of strength has nothing to do with strength as that term is used in the ‘446 patent. Without question, the patent’s description of strength is speaking of tensile strength of the materials, going so far as to describe the specific

amount of yarn tenacity that is desired. Reply Ex. 4 at col. 4, ll. 36-39. *See also* Def.'s Reply at 7-8, and support cited therein.

Mitek Fact #138: Disputed. This statement misrepresents Mr. Grafton's testimony. Mr. Grafton was very clear that PET was added to the braid to improve knot security. Reply Ex. 3 at 53:8-19. Mr. Grafton explained that a purpose of adding PET was to improve the knot security of the braid (Reply Ex. 3 at 53:8-19, 53:24-54:5), and he was not testifying that PET was added to improve the strength of the braid. Mr. Grafton said the exact opposite -- that the strength of the braid, without PET, was excellent. Reply Ex. 3 at 45:16-46:9.

Mitek Fact #139: Undisputed.

Mitek Fact #140: Disputed. This statement misrepresents Mr. Grafton's testimony and is designed to mislead the Court. Mr. Grafton was very clear that the strength of the 100% UHMWPE braid was excellent, however, the knot slippage (knot security) was very poor. Reply Ex. 3 at 46:7-9.

Mitek Fact #141: Disputed. *See* Response to Mitek Fact #130. This statement also misrepresents Mr. Grafton's testimony. Mr. Grafton was very clear that PET was added to the braid to improve knot security. Reply Ex. 3 at 53:8-19. Mr. Grafton never used the term "knot holding strength." Mr. Grafton never testified that Arthrex ever considered a braid of "PET with lubricious PE" because the substance that Arthrex considered to braid with PET was UHMWPE which is not "PE' as that term is used in the '446 patent. Reply Ex. 3 at 53:8-19. *See* Response to Mitek Facts #130 and #134.

Mitek Fact #142: Disputed. This statement is designed to mislead the Court. See Responses to Mitek Facts #136, #140, #141.

Mitek Fact #143: Disputed. This statement is taken out of context and designed to mislead the Court. The '234 patent states that "[s]uture strength is an important consideration in

any surgical suture material" and that UHMWPE is "much stronger than ordinary surgical suture." Reply Ex. 24 at col. 1, ll. 13-14, l. 17-18. Moreover, Arthrex "admitted" to nothing because DePuy Mitek's alleged out of context assertion has nothing to do with any legitimate fact or issue for which it tries to use it.

Mitek Fact #144: Disputed. This statement is out of context and designed to confuse and mislead the Court. Mr. Grafton testified that knot tie-down is an attribute of the suture. Reply Ex. 3 at 28:22-29:2. DePuy Mitek misrepresents Mr. Grafton's testimony as referring to "strength" in the mechanical sense. Strength as an attribute has nothing to do with the '446 patent. This statement is also taken out of context. Mr. Grafton clearly testified that knot tie down is not the same thing as knot strength and that it is the ability to "shift tissue in the position that the surgeon would like for it to be on the bone." Reply Ex. 3 at 27:11-14.

Mitek Fact #145: Disputed. This statement is out of context and designed to confuse and mislead the Court. *See* Response to Mitek Fact #130, #135, #141. The '234 patent never says "PE" is a component of FiberWire and the cited portion of the '234 patent states that "[t]he Dyneema component of the present invention provides strength, and the polyester component is provides to improve its tie ability and tie down characteristics."

Mitek Fact #146: Disputed. *See* Response to Mitek Fact #130.

Mitek Fact #147: Disputed. The first set of yarns is comprised of the seven specific materials set forth in the claims. The patent leaves no doubt that a function of those materials is "to improve the overall pliability" of the braid. Reply Ex. 4 at col. 4, ll. 12-13. Further, Dr. Brookstein admitted that under his analysis any material would meet his functional identity as long as it contributed anything to the suture different from the second yarn. *See* Def. S. J. Mem. at 12 and citations therein. As the application was originally filed, it included broad claims which required only that there be two dissimilar yarns in direct intertwining contact. These

original claims did not identify any specific materials. Defendants' *Markman* Ex.[3] 6 at 18-20. But Ethicon abandoned these claims and instead only pursued the narrower claims which did identify the specific materials in each set of yarn. Opp.Ex. 27. Dr. Brookstein's analysis ignores the fact that these claims are not the claims at issue here.

Mitek Fact #148: Disputed. *See* Response to Mitek Fact #147.

Mitek Fact #149: Disputed. *See* Response to Mitek Fact #147.

Mitek Fact #150: Disputed. *See* Response to Mitek Fact #130, #136, #147.

Mitek Fact #151: Disputed. This statement is designed to mislead the Court. FiberWire does not have "PE" as that term is used in the '446 patent. *See* Response to Mitek Fact #130.

Mitek Fact #152: Disputed. This aspect of the '446 patent has nothing to do with the claims as issued, but only refers to the broad claims that were abandoned during prosecution in favor of the narrower claims which, among other things, identified the specific materials that constitute the first and second set of yarns. Opp.Ex. 27.

Mitek Fact #153: Disputed. *See* Response to Mitek Fact # 152.

Mitek Fact #154: Disputed. *See* Response to Mitek Fact #132.

Mitek Fact #155: Disputed. This statement is designed to mislead the Court. Arthrex does not rely on one sentence of the '446 patent for its defenses in this case. Rather, Arthrex relies on the teachings of the entirety of the '446 patent disclosure. In addition, compliance is used as a synonym for pliability in this sentence of the '446 patent.

Mitek Fact #156: Disputed. *See* Response to Mitek Fact #155.

Mitek Fact #157: Undisputed.

[3] "Defendants' *Markman* Ex." refers to exhibits attached to Defendants' Opening Brief on Claim Construction.

Mitek Fact #158: Disputed. This statement is designed to mislead the Court. *See* Response to Mitek Fact #132.

Mitek Fact #159: Disputed. *See* Response to Mitek Fact #132.

Mitek Fact #160: Disputed. No definition of "weak" is provided. Further, Dr. Brookstein admitted that the same reference he relied upon shows that polypropylene is weaker than polyester. Reply Ex. 5 at 357:12-359:14.

Mitek Fact #161: Disputed. There is no evidence that UHMWPP is commercially available in any form, much less in fiber form.

Mitek Fact #162: Disputed. This statement is designed to mislead the Court. Dr. Brookstein makes up the word "knot holding strength" to describe what is the well-known property of knot security. DePuy Mitek asserts that "[k]not holding strength is a recognized suture strength property," however, its sole support for that statement is Dr. Brookstein's declaration where he cited absolutely nothing for this made up term. Reply Ex. 2 at ¶ 20. What Dr. Brookstein describes as a strength is a made up term that has nothing to do with strength and certainly has nothing to do with strength as that term is used in the '446 patent. Without question, the patent's description of strength is speaking of tensile strength of the materials, going so far as to describe the specific amount of yarn tenacity that is desired. Reply Ex. 4 at col. 4, ll. 36-39. In addition, there is no evidence that the '446 patent is referring to "compression." *See* Response to Mitek Fact #132, #137.

Mitek Fact #163: Disputed. *See* Response to Mitek Fact #130. This statement is vague and designed to confuse the Court. The term "lubricious" is not quantified, therefore, there is no way to compare.

Mitek Fact #164: Disputed. This statement is unintelligible. To the extent that defendants can comprehend this statement, DePuy Mitek is saying that UHMWPE, which is a

very stiff substance, that it has poor pliability, is also a pliable substance within the meaning of the '446 patent. That is physically impossible. *Markman* Reply Ex.[4] 3 at 299:1-3. *See also* Reply Ex. 23 at ¶¶ 4-5, and exhibits cited therein. *See also* Opp. Ex. 17 at 306:20-307:4. *See also* Response to Mitek Fact # 132.

Mitek Fact #165: Disputed. This statement is incomplete and misleading. *See* Response to Mitek Fact #132, #164.

Mitek Fact #166: Disputed. This statement is vague and confusing and designed to mislead. The statement contains a series of undefined terms. Moreover, the statement implies that detracting from knot security is a "purpose," and is therefore unintelligible. It is undisputed that UHMWPE the purpose of UHMWPE was to add tensile strength to FiberWire.

Mitek Fact #167: Undisputed.

Mitek Fact #168: Disputed. Dr. Burks conducted blind tests on coated and uncoated FiberWire suture, testing tactile feel and knot tie down characteristics, both in connection with his expert report and also at his deposition. Reply Ex. 10; Reply Ex. 11 at 98:10-14, 20-23.

Mitek Fact #169: Disputed. Dr. Burks got the test right all six times he performed the tests both at his deposition and in preparation of his report. Reply Ex. 10; Reply Ex. 11 at 98:10-14, 20-23. Dr. Burks never said he "could not clearly feel a difference" between the two sutures. Rather, Dr. Burks stated that he was able to feel that the coated sutures were "generally smoother" than the uncoated sutures. Reply Ex. 11 at 88:10-13.

Mitek Fact #170: Disputed. This testimony is taken out of context and is designed to mislead the Court. Dr. Burks testified to the obvious; if he did *a hundred* tests, he might not get it correct *every time*. DePuy Mitek Opp. at 16. *See* Response to Mitek Fact # 169.

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[4] "*Markman* Reply Ex." refers to exhibits attached to Defendants' Reply in support of their Opening Brief on Claim Construction.

Mitek Fact #171: Disputed. There is no evidence regarding how "surgeons normally handle FiberWire in the surgical environment."

Mitek Fact #172: Disputed. *See* Response to Mitek Fact #169. Also, Dr. Burks did not "admit" anything. He simply speculated that might be the case.

Mitek Fact #173: Disputed. This testimony is taken out of context and designed to mislead the Court. *See* Responses to Mitek Facts #169 and #172.

Mitek Fact #174: Disputed. This statement is designed to mislead the Court. "Monofilament-like coating" is undefined. Further, DePuy Mitek asserts that the '446 patent only criticizes undefined "heavy coatings" and not FiberWire's type of coating. DePuy Mitek Opp. at 18. However, the '446 patent criticizes "thermoset" coatings "which require[] a curing step for proper application." Reply Ex. 4 at col. 1, ll. 52-54. FiberWire's coating is also a thermoset coating. Reply Ex. 14 at 95:5-7. In addition, there is no evidence that the FiberWire coating is applied that it is just a "surface lubricant." The FiberWire coating affects the pliability of the suture braid and the knot strength of the suture. Reply Ex. 6 at 22-29.

There is also no basis for the assertion that the FiberWire coating is applied thinly to the braided suture. While Dr. Brookstein's analysis showed that the coating constituted 3.4% volume of the FiberWire suture, he provided no basis for his conclusion that this is a "small" amount. All the evidence is to the contrary. The patents in the field show that this is more than enough to materially affect the handleability aspects of the suture. Reply Ex. 12 at col. 2, ll. 46-49 (disclosing about 0.01 to about 0.1 weight percent coating, and preferably about 0.02 to about 0.5 weight percent coating); Reply Ex. 13 at col. 3, l. 62 – col. 4, l. 1 (shows coating compositions in the amount of up to 0.25% by weight).

Mitek Fact #175: Disputed. *See* Response to Mitek Fact #174.

Mitek Fact #176: Disputed. This is Dr. Brookstein's "magic" and "miracles" argument where coating could only affect the basic and novel characteristics if "the coating in some *miraculous* way made those materials not yarns anymore" or "all of a sudden you had a set from A, a set from B and now if was some *magical* structure that wasn't yarns, it wasn't two sets, they were all the same, that would be a transformation." Such analysis has nothing to do with the claims of the '446 patent. Reply Ex. 5 at 398-399. *See also* Response to Mitek Fact # 152, #174.

Mitek Fact #177: Disputed. FiberWire is coated with a silicone coating, however, there is no reliable evidence that the coating is only on the surface. *See* Response to Mitek Fact # 174.

Mitek Fact #178: Disputed. The '446 patent states that coating can "further improve the handleability and knot tiedown performance of the braid." The patent also teaches that "if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricious yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening. Reply Ex. 4 at col. 6, ll. 7-9, 13-17.

Mitek Fact #179: Disputed. The '446 patent does not support this statement. Further, the term "heavy coatings" is not used in the '446 patent, therefore, this statement is unintelligible. *See* Response to Mitek Fact # 174.

Mitek Fact #180: Disputed. Dr. Mukherjee merely responded in the negative to a question asking "does the coating on FiberWire prevent the PET fibers, PET or ultra high molecular weight polyethylene fibers from providing contribution to FiberWire's properties. Reply Facts Ex.[5] 1 at 563:20-25. He never testified that coating on FiberWire does not materially affect its novel and basic characteristics, as they are defined by Mitek. In addition,

[5] "Reply Facts Ex." refers to exhibits to Defendants' Reply Facts.

Dr. Brookstein's affidavit does not dispute that PET is included in FiberWire to improve handleability characteristics nor does he dispute the overwhelming evidence that coating materially affects such characteristics. Reply Facts Ex. 2 at ¶¶ 43-54. *See also See* S.J. Ex.[6] 45 at ¶ 15. *See also* Reply Ex. 24. *See also* S. J. Ex. 34, col. 1, ll. 14-18 ("a multifilament suture typically requires a surface coating to improve the tactile smoothness, pliability and tiedown performance of the suture"); S. J. Ex. 35, col. 1, ll. 11-15 (same); S. J. Ex. 36, col. 1, ll. 12-15 ("multifilament suture typically require a surface coating to improve the pliability and knotting characteristics of the suture"). *See also* S. J. Ex. 37, col. 1. ll. 19-25 ("It has therefore become a common practice to coat sutures, particularly those of the multifilament variety, with compositions which improve their knot tie-down performance and perhaps one or more other properties of the sutures as well"). *See also* S. J. Ex. 29 at 11 ("Multifilament sutures may also be coated to help them pass relatively smoothly through tissue and enhance handling characteristics."). *See also* S. J. Ex. 28 at 525 ("synthetic sutures have been coated to decrease their coefficient of friction and improve their handling characteristics."). *See also* S. J. Ex. 39 (Orthocord is coated "for improved slide ability and enhanced knot tying characteristics (*e.g.* knot slide)."); S. J. Ex. 40 ("The purpose of coating the Panacryl suture is to provide the suture with handling properties."). *See also* S. J. Ex. 4 at 64:12-24; S. J. Ex. 41 at 48:11-49:2; S. J. Ex. 31 at 167:1-13; S. J. Ex. 18 at 295:23-296:7; S. J. Ex. 42 at 63:10-23.

Mitek Fact #181: Undisputed.

Mitek Fact #182: Undisputed.

Mitek Fact #183: Disputed. This statement is out of context and designed to mislead the Court. The claims in the FiberWire patent describe a core of UHMWPE surrounded by a braided sheath (called a "cover" in the claims) of UHMWPE and polyester. Reply Ex. 24 at col.

[6] "S. J. Ex." refers to exhibits attached to Defendants' Summary Judgment Motion.

3, l. 13 – col. 4, l. 23. In distinguishing this configuration from the '575 patent, Arthrex's counsel stated that examples discussed in the '575 patent not do not disclose a core of UHMWPE and a braided sheath which included both UHMWPE and polyester. Reply Ex. 25 at 5. Arthrex's counsel was silent on the specific issue involved here, that is, the combination of a braid of UHMWPE and polyester without the need for a core, which is confirmed by the testimony of Arthrex's counsel. Reply Ex. 26 at 107:6-20.

Mitek Fact #184: Undisputed. This, however, was not an admission as Dr. Brookstein explained that PET and polyester in this art are synonymous. Opp.Ex. 4 at 54:4-6.

Mitek Fact #185: Disputed. This statement is out of context and designed to mislead the Court. Dr. Mukherjee's testimony related only to Arthrex's attorney's statements when seeking the FiberWire patent which was consistent with defendants' positions in this case. *See* Response to Mitek Fact #183.

Mitek Fact #186: Disputed. This statement is incomplete and out of context and designed to mislead the Court. DePuy Mitek's description of the spiroid braid of Figure 6 is wrong because it also discloses that non-absorbable materials can be used with UHMWPE. Reply Ex. 20 at col. 4, ll. 8-24. Moreover, Defendants point to Figure 6 for the sole purpose of showing an additional example of direct intertwining contact (Def. S. J. Mem. at 23), a fact that even DePuy Mitek does not dispute. Defendants' invalidity argument is based on claim 11 or 12 of the '575 patent, dependant claims that also include claim 1. *See also* Def.'s Reply at 17-18, and support cited therein.

Mitek Fact #187: Disputed. *See* Response to Mitek Fact # 130, #186.

Mitek Fact #188: Disputed. The '575 patent refers to every embodiment (called an elongated structure in the claims of the '575 patent) as a suture (Reply Ex. 20 at Title, col. 1, l. 7, col. 2, l. 62 – col. 3, l. 19, col. 5, l. 55, col. 7, l. 26, 43, 50, col. 8, l. 23) and Dr. Hermes admitted

that the disclosed elongated structures are called sutures in the '575 patent. *See* Def. S. J. Mem. at 22.

Mitek Fact #189: Disputed. Mr. Soffen advised his client that the use described in the claims of the 575 patent was different from the uses of FiberWire and thus, FiberWire did not infringe the claims of the '575 patent. Reply Ex. 21. He never said that "the 575 Patent claims do not describe the use of a suture" and DePuy Mitek points to no evidence where such a statement was made.

Mitek Fact #190: Disputed. This assertion is incomplete because the claim also includes a suture that has every limitation of claims of the '446 patent (if "PE" in the '446 patent were construed to include UHMWPE). Reply Ex. 20 at claim 12.

Mitek Fact #191: Disputed. Claim 1 of the '575 patent states that the two materials "are braided to form" the elongated member. Reply Ex. 20 at col. 8, ll. 37-38. this is direct intertwining contact. Reply Ex. 6 at 14-16. Dr. Hermes could not provide a single example of a braided construction that was not braided in direct intertwining contact. S. J. Ex. 10 at 212:25-213:5.

Mitek Fact #192: Disputed. *See* Response to Mitek Fact #191.

Mitek Fact #193: Disputed. See Response to Mitek Fact #191. Further, Dr. Hermes admitted that claim 1 of the '575 patent included configurations where there was no core. Reply Ex. 22 at 199:14-18. Thus, DePuy Mitek's own expert admitted, claim 1 of the '575 patent includes configurations other that the core/sheath arrangement of Figures 8 and 9.

Mitek Fact #194: Disputed. This statement is incomplete and out of context. Further, the word "sterilized" is not italicized in the claim.

Mitek Fact #195: Undisputed.

Mitek Fact #196: Disputed. This statement ignores the fact that the '575 patent discloses combinations that include a volume fraction of the first fiber-forming material between about 20-80%. Def. S. J. Mem. at 26. *See also* S. J. Ex. 15 at col. 4, ll. 8-24; FIG. 6; S. J. Ex. 10 at 207:12-21.

Mitek Fact #197: Disputed. The evidence shows that braids, and not the claimed "sutures," were made. DePuy Mitek never reduced to practice the claimed invention because the claims of the '446 patent require sterilization and the braids that Ethicon built were never sterilized. Def. S.J. Mem. at 20-21. See also S. J. Ex. 19 at 225:5-8; S. J. S. J. Ex. 10 at 345:7-10.

Mitek Fact #198: Disputed. This statement is designed to mislead the Court. While it is correct that sterilization is a well known, commercialization step in suture development, that has nothing to do with DePuy Mitek's reduction to practice contention. Reduction to practice law requires *both* that the embodiment that is built meets all the limitations of the claims *and* that it be shown that the invention would work for its intended purpose. Whatever relevance DePuy Mitek's argument may have to the *second* prong (that the invention works for its intended purpose), it is irrelevant to the first prong and does not change the undisputed facts showing that the braids that Ethicon built did not meet all the limitations of the claims. *See also* Def.'s Reply at 15-16, and support cited therein.

Mitek Fact #199: Undisputed.

Mitek Fact #200: Disputed. Speculation on what Dr. Steckel "would" have done cannot be the subject of an undisputed fact.

Mitek Fact #201: Disputed. The evidence is that the earliest the inventors conceived of the invention of the '446 patent was June 1988.

Mitek Fact #202: Disputed. DePuy Mitek never produced the alleged draft application, so there is no way of knowing what was in the application and what relationship it has to the application as filed. Mr. Goodwin, the alleged actor, could not testify that he acted diligently because he did not remember if there was a draft application and had no idea if he ever prepared one or got any comments from the inventors. Reply Ex. 17 at 77:18-21; 78:4-7. Moreover, a document that DePuy Mitek did produce that discusses actions by Ethicon conclusively shows the *opposite* of diligence; it shows that Ethicon delayed. Reply Ex. 18. Finally, DePuy Mitek gets the date to which it must show diligence wrong because the undisputed evidence of record shows that the '575 patent was conceived of a year or more before the '575 patent application was filed. Reply Ex. 19 at 33:15-34:4.

Mitek Fact #203: Disputed. *See* Response to Mitek Fact #202.

Mitek Fact #204: Disputed. *See* Response to Mitek Fact #202.

Mitek Fact #205: Disputed. This statement is designed to mislead the Court. The '446 patent makes clear that the lubricious materials are highly pliable and add to pliability. *See* Response to Mitek Fact #132.

Mitek Fact #206: Disputed. This statement is designed to mislead the Court. *See* Response to Mitek Fact #132.

Mitek Fact #207: Disputed. This statement misrepresents the '446 patent. Reply Ex. 6 at 6. *See* Response to Mitek Fact #132.

Mitek Fact #208: Disputed. This statement misrepresents the '446 patent. *See* Response to Mitek Fact #132.

Mitek Fact #209: Disputed. This statement misrepresents the '446 patent. *See* Response to Mitek Fact #132, #152.

Mitek Fact #210: Disputed. *See* Response to Mitek Fact #130. Dr. Brookstein never disagrees that UHMWPE is stiff and that, in FiberWire, PET (the material from the second set of yarns), not UHMWPE, is included to increase pliability. Def. S. J. Mem. at 11 and fact cited therein. See Response to Mitek Facts # 143, #145, #166.

Mitek Fact #211: Disputed. This statement is designed to confuse and mislead the Court. A material cannot be both pliable and stiff at the same time, the two are polar opposites, as the '446 patent itself teaches. Reply Ex. 4 at col. 8, ll. 41-42 ("[b]ending rigidity is the inverse of pliability"). *See* Response to Mitek Fact #164.

Mitek Fact #212: Disputed. *See* Response to Mitek Fact #211.

Mitek Fact 213: Disputed. The evidence is that the earliest the inventors conceived of the invention of the '446 patent was June 1988.

Mitek Fact #214: Undisputed.

Dated: September 15, 2006

Respectfully submitted,

By: /s/Charles W. Saber

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Defendants' Reply to Mitek's Facts Submitted in Response to Arthrex's Summary Judgment Motion was served, via the Court's email notification system on the following counsel for Plaintiff on the 15th day of September 2006:

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Exhibit 1

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

Civil Action No. 04-12457 PBS

DEPUY MITEK, INC., a Massachusetts Corporation,

Plaintiff,

v.

ARTHREX, INC., a Delaware Corporation

Defendant.

Videotaped Deposition of DEBI PRASAD MUKHERJEE

- VOLUME TWO -

Washington, DC

Wednesday, June 14, 2006

The videotaped deposition of DEBI PRASAD MUKHERJEE, Volume Two, was held on Wednesday, June 14, 2006, commencing at 9:12 a.m., at the offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street, Northwest, Washington, DC, before Mary Ann Payonk, RDR, Certified Realtime Reporter, Registered Diplomate Reporter and Notary Public.

MR. TAMBURO: Objection, vague.

A Enough information for a scanning microscopy is not very conclusive. They may or may not be.

BY MR. BONELLA:

Q You don't know?

A I don't know.

Q Okay. Does the coating on FiberWire prevent the PET yarns and the PTFE yarns from each providing their individual properties to FiberWire?

MR. TAMBURO: Objection, vague.

THE WITNESS: Now please correct me.

MR. TAMBURO: And -- and -- and -- and --

THE WITNESS: FiberWire does not contain a PTFE.

BY MR. BONELLA:

Q Oh, I'm sorry. Did I misspeak?

A You just said that.

Q I'm sorry.

Does the coating on FiberWire prevent the PET fibers, PET or ultra high molecular weight polyethylene fibers from providing contribution to FiberWire's properties?

MR. TAMBURO: Objection, vague.

A No.

Exhibit 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.,** **a Private Limited Company** **of the United Kingdom,** **Defendants.**	)	**Civil No. 04-12457 PBS**

Declaration of Dr. David Brookstein In Support of DePuy Mitek's
Claim Interpretation of the Hunter Patent and Summary Judgment of Infringement

I. Background Information

A. Teaching Experience

1. I am the Dean and Professor of Engineering at the School of Engineering and Textiles of Philadelphia University. I have held this position since 1994. In 2005, I also was appointed Executive Director of Research at Philadelphia University.

2. I was a Visiting Scholar at the Harvard University Center for Textile and Apparel Research (Division of Engineering and Applied Sciences) between 2002-2003.

3. I was an Adjunct Professor in Mechanical Engineering at Northeastern University in Boston, MA from 1981-1983. At Northeastern, I taught undergraduate courses in statics, dynamics, and mechanics of deformable bodies and material science.

4. I was Assistant Professor of Textile Engineering at Georgia Institute of Technology, College of Engineering from 1975 – 1980. At Georgia Tech, I taught and conducted research in

structure like FiberWire is dependent upon many factors including the number of filaments, the modulus of elasticity in tension and compression, the fiber-to-fiber mobility, and the individual moment of inertia of each filament, the manner in which the materials are braided, and material lubricity. As the 446 Patent explains, material lubricity permits fiber-to-fiber mobility, so that when the braid is bent the fibers can easily bend and slide past other fibers. Thus, even accepting that ultra high molecular weight PE is "stiff," Arthrex's counsel assertions that it does not improve overall braid pliability are just wrong.

42. Arthrex's argument is basically the same concept that I addressed before when Arthrex's expert incorrectly assumed that FiberWire is a monofilament structure. As I explained previously, FiberWire is neither a monofilament nor a pure multifilament structure. Arthrex's statement that FiberWire's PE does not improve braid pliability basically makes a similar mistake and incorrectly assumes that FiberWire is a monofilament type structure.

IV. Under Arthrex's Definition of "Consisting Essentially Of," FiberWire Infringes Claims 1, 2, 8, 9, and 12 of the 446 Patent

43. As I understand the law, because the 446 Patent claims recite the phrase "consisting essentially of," if FiberWire has structure in addition to the structure listed in the 446 Patent claims, there is infringement, unless the additional structure materially affects the "basic and novel characteristics" of the claimed suture. I understand that Arthrex contends that the "basic and novel characteristics" of the suture claimed in the 446 Patent are "a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties" (Arthrex Br. at 13). Arthrex asserts that that FiberWire's coating materially affects this novel and basic characteristic because it materially affects handleabilty and knot tie down properties (Arthrex Br. at 13-14). I disagree for the following three reasons: (i) FiberWire was specifically engineered to have the properties

described in the 446 Patent; (ii) the 446 Patent does not consider coating of the type used on FiberWire to have a "material" affect on the basic and novel characteristics; and (iii) Dr. Burks' tests and analyses show that FiberWire's coating does not materially affect handleability. I describe each of these three points below.

1. FiberWire Was Engineered to Have The Basic and Novel Characteristics, and the Coating Does Not Materially Affect Them

44. FiberWire's coating does not materially affect FiberWire's characteristics of having two dissimilar yarns (*i.e.*, UHMWPE and PET) braided together to achieve improved handleability and pliability performance without significantly sacrificing physical properties. Both before and after the coating is applied to FiberWire, FiberWire has two dissimilar yarns (*i.e.*, UHMWPE and PET). Further, regardless of the coating, the UHMWPE and PET braid provides improved handleability and pliability performance without significantly sacrificing physical properties. The coating does not prevent or materially affect the two materials from being dissimilar, from being braided, or from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words because FiberWire still obtains the handleability/physical property benefits of the UHMWPE/PET braid after the coating is applied, the coating does not materially affect the novel and basic characteristics. FiberWire's coating is merely a surface "lubricant" (Ex. 15).

45. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, or from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is supported by Arthrex's development and testing of FiberWire. Arthrex and Pearsalls had originally developed a suture having a homogeneous 100% UHMWPE braid. But they found it to have unacceptable knot holding strength properties (Ex. 3 at 52:24-53:7). The

homogeneous UHMWPE braid was too lubricous to "hold a knot" (*id.* at 45:16-46:15; 50:1-53:7). At the same time, Arthrex found that the same braided UHMWPE suture had other good "strength" properties (Ex. 3 at 46:7-8). I consulted with Dr. Hermes and, based on his opinion and because UHMWPE fibers are lubricous (*id.* at 52:24-53:1), the UHMWPE braid would also have had some good handling properties including surface frictional properties, such as tactile feel. Also, the lubricous yarns would contribute to braid pliability because they allow the fibers to slide past each other when bent. Arthrex and Pearsalls also developed sutures having homogeneous polyester braids (Ex. 16). According to Mr. Grafton, Arthrex found them to have lower knot pull strength than a braid of UHMWPE fibers and polyester fibers (Ex. 16; Ex. 3 at 81:8-12). Thus, Arthrex thought that sutures having braids of UHMWPE and braids of polyester each had different drawbacks. Ultimately, Mr. Grafton braided UHMWPE with PET, which is a polyester, and found that the heterogeneous braid had improved knot holding strength properties; it did not slip like the UHMWPE braid he had made:

Q. And was the knot slippage of this ultra-high molecular weight polyethylene poor security because of the lubricity of polyethylene?
A. Yes.
Q. Yes?
A. Yes.
Q. So then you came up with the idea to braid PET with the ultra-high molecular weight polyethylene to reduce the knot slippage?
A. Yes.
Q. And when you say knot slippage, we're referring to this knot security test?
A. Yes.
Q. So are we using the terms knot slippage and knot security interchangeably here?
A. You are, yes.
Q. In your testimony?
A. Yes.
Q. So the knot security of the 100 percent ultra-high molecular weight polyethylene was poor, the

prototype; right?
A. Yes.
Q. And your idea was to add the PET and to improve the knot security?
A. I've lost count, it's been so many times, but the answer again is yes.

(Ex. 3 at 53:2-54:5) (objections omitted). This type of UHMWPE and PET braid was ultimately marketed as FiberWire. Thus, Arthrex engineered a braid of UHMWPE and PET to maximize the benefits of the dissimilar yarns (Ex. 3 at 68:25-70:12). For example, UHMWPE in FiberWire's braid contributes to the braid's tensile strength, knot pull strength, pliablity, and lubricity/handling, and PET contributes to the braid's knot holding strength, and handling/pliability. Thus, Arthrex designed FiberWire to be braid of dissimilar yarns that has improved handleability and pliability performance without significantly sacrificing physical properties. Although FiberWire is coated, it is still a braid of dissimilar yarns having these benefits. Although the coating may enhance certain suture properties, the coating does not materially affect the fact that FiberWire has a braid with improved handleability and pliability performance without significantly sacrificing physical properties.

46. My opinion that FiberWire was specifically designed to have the novel and basic characteristics that Dr. Mukherjee attributes to the 446 Patent is further supported by other aspects of FiberWire's development. For example, during FiberWire's initial development, Mr. Grafton asked Pearsalls to "build a 25% Dyneema/75% polyester *blend* in a size 2 that is *very flexible* (like the existing suture or the [E]thicon sample)" (Ex. 6) (emphasis added). As Mr. Grafton stated, "[i]f we can get this blend correct, we will have a terrific advancement" (Ex. 6). According to Mr. Grafton, Arthrex varied the dissimilar braid materials in type and amount in order to optimize FiberWire's properties:

Q. I would like to know what you mean by in your

letter when you said, "If we can get this blend correct." You asked them for a 25 percent Dyneema/75 percent polyester blend in Size 2 that's very flexible. And then you said, "If we can get this blend correct, we will have a terrific advancement." What did you mean by "If we can get this blend correct"?

A. The optimization of the two materials. If you had the knot strength, loop security, and tensile strength, as well as the tactile feel of the suture all superior to what was on the market, then it would be a superior product.
Q. Wait a second. You said optimization of two materials.
A. (Witness nods head affirmatively).
Q. At this point in time, November 1998, were you trying to vary the amount and type of the Dyneema and polyester in the braid in order to get the best properties?
A. During -- during the -- during that period of time, yes.
Q. So you were balancing off the properties of each material to try to get the optimum properties --
A. Tensile strength.
Q. To get the optimum tensile strength?
A. (Witness nods head affirmatively).
Q. What about knot security?
A. Yes.
Q. Okay. So you were varying the amount and type of the materials to get the optimum knot security, optimum tensile strength?
A. Yes.
Q. Any other properties? Knot tiedown?
A. The slideability of the knot, the tactile feel in the surgeon's hands of the material.
Q. So you were varying type and proportion of the materials to optimize all these properties in the product?
A. Yes.

(Ex. 3 at 68:25-70:13). Further, as explained by Ms. Holloway, FiberWire was braided, so that the individual materials contribute to FiberWire's handleability:

Q. What materials contribute to the handleability of Arthrex's FiberWire sutures?
A. All materials used.

(Ex. 17 at 31:23-25). Thus, in designing FiberWire to have a dissimilar yarn braid, Arthrex specifically designed FiberWire to have the basic and novel characteristics that Dr. Mukherjee attributes to the 446 Patent: (i) a dissimilar yarn braid having the benefits of each yarn; and (ii) improved handleability and pliability without significantly sacrificing physical properties. Although FiberWire is coated, it still reaps the benefits of this dissimilar yarn braid in terms of handleability/pliability and physical properties. Therefore, the coating does not materially affect the novel and basic characteristics as defined by Dr. Mukherjee.

47. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, and from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is further supported by the fact that FiberWire has a very small amount of coating. In fact, it is so small that Pearsalls and Arthrex consider it unmeasureable (Ex. 5 at 119:5-9; Ex. 8 at 94:2-9; Ex. 18 at 48:1-50:16; Ex. 19 at ARM002104). I have personally observed and studied Pearsalls' coating processes for FiberWire during an inspection of Pearsalls' facilities in January 2006. FiberWire is coated by passing a braid of PET and UHMWPE, which has been dyed[3] and scoured, through a bath of NuSil Med 2174 polymer and Xylene solvent at a rate of 20 meters per minute (Ex. 5 at 88:4-9; 82:14-18). Xylene is not a coating. Rather, Xylene is a solvent that dissolves the Med NuSil polymer, so that it can adhere to the FiberWire braid (Ex. 5 at 87:25-88:3; Video of Pearsalls' manufacturing). After passing through the solution, the coated FiberWire is passed through pads, which are compressed together, to wipe away excess coating (Ex. 5 at 97:1-18). Further, FiberWire is passed through a five-stage oven that dries the coating and evaporates the solvent (Ex. 5 at 95:14-17). The process is then repeated. I have measured

[3] Most FiberWire is dyed blue. But some, such as TigerWire is not. Also, TigerWire has a braid that includes a Nylon marker band in place of one PET yarn.

the amount of coating by weight on FiberWire by determining the linear density (*i.e.*, grams/unit length) of a sample that was not coated, a sample that had been coated once, and sample that had been coated twice (DMI Exhibits 284, 342, and 285, Exs. 20, 21, and 22, respectively). I determined that the linear density of DMI Ex. 284 (uncoated) is 2393 denier, DMI Ex. 342 (coated once) is 2474 denier, and DMI Ex. 285 (coated twice) is 2508 denier using a traditional Mettler balance housed at the Philadelphia University Research Center Materials Evaluation Laboratory. Accordingly, the linear density of DMI Ex. 342 indicates a 3.4% pick-up of coating material from the uncoated DMI Ex. 284. The linear density of Ex. 285 indicates a 1.4% pick-up of additional coating material from DMI Ex. 342. Thus, the total pick-up of Ex. 285 over DMI Ex. 284 is approximately 4.8%. The result of this coating process is that, although FiberWire has a very small amount of coating, FiberWire still has two dissimilar yarns braided together to form a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words, the coating did not transform the braided FiberWire materials into another structure or cause it to lose its characteristics that are attributable to the dissimilar yarns being braided. For example, the coating is not applied in a very thick layer and then melted together with the yarns to form a non-braided structure. As Arthrex explains in its instructions for use, FiberWire's coating is just a "lubricant" (Ex. 15).

48. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, and from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is supported by both my visual observations of FiberWire, as well as those by CETR. Both my photographs and CETR's show that, even at extreme magnifications, it is difficult to even see coating in certain areas of the suture. In fact, both sets of pictures show that FiberWire

has fibers that retain their morphological attributes, so that they can contribute to the handleability, pliability, and physical properties of FiberWire.

49. I note that Arthrex does not address the issue of whether FiberWire's coating materially affects the fact that it has a dissimilar yarn braid with improved handleability and pliability without significantly sacrificing physical properties. Rather, Arthrex only asserts that FiberWire's coating affects certain individual properties. But that is not the relevant issue even as Arthrex defined the novel and basic characteristics. Rather, the relevant issue as Arthrex framed it was whether FiberWire's coating materially affected FiberWire from being a suture with "two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties" (Arthrex Br. at 13). In my opinion, because FiberWire is specifically designed to have precisely these characteristics and its coating is essentially a surface lubricant, FiberWire's coatings effects are not material to the novel and basic characteristics.

2. Based on the 446 Patent, FiberWire's Coating Does Not Materially Affect the Novel and Basic Characteristic

50. In order to determine whether an effect on the basic and novel characteristics, as those terms are defined by Arthrex, is "material," I have consulted the 446 Patent to determine what it considers "material" or not "material." In other words, I have considered whether FiberWire's coating is "material" in the context of the invention described in the 446 Patent. Based on the 446 Patent's description of the invention and its description of coatings, FiberWire's coating does not "materially" affect the novel and basic characteristics, as defined by Arthrex.

51. My opinion that FiberWire's coating does not have a "material" effect is based on the 446 Patent's explanation that "coating" is not "material" to the invention. As the 446 Patent explains, the direct intertwining braid of dissimilar materials provides "outstanding properties

attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns" (Ex. 2 at 2:50-52). The 446 Patent further explains that such a braid can be further improved with a coating (*id.* at 6:5-21). Thus, because the 446 Patent specifically contemplates applying coatings of the type used in FiberWire to refine certain braid properties, the 446 Patent does not consider coatings, of the type applied to FiberWire, to have a "material" effect on the basic and novel characteristics of the suture claimed in the 446 Patent.

52. I disagree with Arthrex that FiberWire's coating has a "material" effect because Arthrex basically *excludes* coated sutures from the 446 Patent claims. But this is just contrary to the teachings of the 446 Patent. As the 446 Patent describes, the inventors specifically contemplated preferred embodiments having coatings:

> If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to ***further*** improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. ***Most preferably***, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating ***may be*** eliminated saving expense as well as avoiding the associated braid stiffening.

(*id.* at 6:5-18) (emphasis added). Thus, the inventors specifically *included* coatings within the description of the invention, not *excluded* them. Therefore, because the 446 Patent specifically contemplated coatings, such as that used in FiberWire, it is my opinion that FiberWire's coating cannot be deemed to have a "material" effect on the basic and novel characteristics of the invention.

53. My opinion that FiberWire's "coating" does not have a "material" effect is further supported by the fact that Arthrex and Pearsalls did precisely what the 446 Patent teaches to obtain the basic and novel characteristics that Arthrex attributes to the suture claimed in the 446 Patent. The 446 Patent teaches forming a heterogeneous braid which has a first and a second set

of continuous and discrete yarns (*id.* at 2:40-42). FiberWire's UHMWPE and PET are braided in a heterogeneous braid and are continuous and discrete yarns. The 446 Patent teaches braiding a lubricous yarn with a yarn of different lubricity (*id.* at 4:11-12; 4:33-40). Arthrex and Pearsalls do that; they braid UHMWPE, a lubricous yarn, with PET, a yarn of different lubricity. The 446 Patent teaches braiding dissimilar yarns in direct intertwining contact (*id.* at 2:43-44). Arthrex and Pearsalls braided PET and UHMWPE yarns in direct intertwining contact (Ex. 8 at 107:5-8). The 446 Patent teaches that each yarn has a plurality of filaments (Ex. 2 at 2:45-48). FiberWire's braided UHMWPE and PET yarns each have a plurality of filaments, as shown in Exs. 20, 21, and 22. The 446 Patent teaches braiding yarns to obtain the benefits of each. Arthrex and Pearsalls do that as is shown by its product development (Ex. 3 at 68:25-70:13). The 446 Patent teaches "to tailor" the physical braid properties "by varying the type and proportion of each of the dissimilar fiber forming materials used" (Ex. 2 at 2:58-61). Arthrex did just that by trying different types and amounts of UHMWPE and polyester (Ex. 3 at 68:25-70:13). The 446 Patent teaches coating the braid by immersing it in a solution of a coating polymer and a solvent (Ex. 2 at 6:9-10). Likewise, Pearsalls and Arthrex coat by passing FiberWire through a coating solution (see above). The 446 Patent specifically contemplates that coating can "***further***" improve the handleability of the suture (Ex. 2 at 6:5-18) (emphasis added). The 446 Patent states a preference that coating does not adhere the yarns or fibers to one another thereby increasing stiffness (Ex. 2 at 6:11-13). As shown by the SEM's of the FiberWire, the fibers are not bonded together (Exs. 20, 21 and 22). Thus, because Arthrex and Pearsalls specifically engineered FiberWire to be a nonabsorbable heterogeneous braid, as is precisely described in the 446 Patent, the effects of FiberWire coating can hardly be considered material.

54. I further disagree with Arthrex's focus on FiberWire's coating with reference to defining what is "material" because the 446 Patent is not about "coating" or eliminating "coatings." Rather, the problem addressed by the 446 Patent is how to improve multifilament braided suture properties. For example, the 446 Patent explains that some prior art attempted to improve braided multifilament suture properties at the expense of restricting the movement of adjacent filaments (Ex. 2 at 1:26-29). The 446 Patent then provides some prior art attempts including a certain polyester coating for multifilament sutures (*id.* at 1:32-43), a PTFE coating (*id.* at 1:43-54), a monofilament like surface on a multifilament braid (*id.* at 1:55-2:2), and an elongated core (*id.* at 2:3-13). According to the 446 Patent, these techniques could be improved upon because they did not focus on improving multifilament properties by increasing fiber-to-fiber mobility (*id.* at 2:14-17). Thus, the 446 Patent is not saying that coating was a problem that had to be solved. Rather, the 446 Patent is teaching that certain coatings and other techniques were insufficient *by themselves* to sufficiently improve certain multifilament suture properties.

55. As a solution to the issue of improving multifilament braided suture properties, the 446 Patent teaches braiding dissimilar fiber-forming materials in direct intertwining contact to form a heterogeneous braid, that has properties "attributable to the specific properties of the dissimilar fiber-forming materials" (*id.* at 2:40-53). The 446 Patent also states that certain properties of the dissimilar yarn braid can be "improved" by a coating (*id.* at 6:5-21). Thus, the solution to the issue of improving multifilament braid properties provided by the 446 Patent is to braid dissimilar fiber-forming yarns in direct intertwining contact. Thus, coatings were not material to the issue addressed by the 446 Patent, nor the solution provided. Therefore, the 446 Patent's description of the invention shows that it does not consider coating, as used on FiberWire, to have a "material" effect on the basic and novel characteristics of the claimed suture.

64. It is my expert opinion and observation that the coating only appears on the surface of the braid.

I declare under penalty of perjury that the foregoing is true and correct.

Date Executed: September 1, 2006

/s/